

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

Track Three Cases

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

**DECLARATION OF STEVEN N. HERMAN IN SUPPORT OF THE PHARMACY
DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS
AND TESTIMONY OF DR. KATHERINE KEYES**

EXHIBIT 15

Industry Payments to Physicians for Opioid Products, 2013–2015

Scott E. Hadland, MD, MPH, MS, Maxwell S. Krieger, BS, and Brandon D. L. Marshall, PhD

Objectives. To identify payments that involved opioid products from the pharmaceutical industry to physicians.

Methods. We used the Open Payments program database from the Centers for Medicare and Medicaid Services to identify payments involving an opioid to physicians between August 2013 and December 2015. We used medians, interquartile ranges, and ranges as a result of heavily skewed distributions to examine payments according to opioid product, abuse-deterrent formulation, nature of payment, state, and physician specialty.

Results. During the study, 375 266 nonresearch opioid-related payments were made to 68 177 physicians, totaling \$46 158 388. The top 1% of physicians received 82.5% of total payments in dollars. Abuse-deterrent formulations constituted 20.3% of total payments, and buprenorphine marketed for addiction treatment constituted 9.9%. Most payments were for speaking fees or honoraria (63.2% of all dollars), whereas food and beverage payments were the most frequent (93.9% of all payments). Physicians specializing in anesthesiology received the most in total annual payments (median = \$50; interquartile range = \$16–\$151).

Conclusions. Approximately 1 in 12 US physicians received a payment involving an opioid during the 29-month study. These findings should prompt an examination of industry influences on opioid prescribing. (*Am J Public Health*. 2017;107:1493–1495. doi: 10.2105/AJPH.2017.303982)

The nonmedical use of opioids and overdose mortality have reached unprecedented levels in the United States.¹ To respond to concerns about overprescribing of opioids, the Centers for Disease Control and Prevention recently released chronic pain management guidelines that call on physicians to consider nonopioid pain medications as an alternative to opioids.² Additionally, some physicians and pharmaceutical industry representatives have suggested that abuse-deterrent formulations—newly marketed brand-name opioids with pill properties that render misuse more difficult—offer a safer option for prescribers.^{3,4}

Under the recently implemented Physician Payments Sunshine Act, drug companies are now required to report all transfers of value (“payments”) to US physicians.⁵ Research suggests that pharmaceutical company payments promote increased prescribing for marketed brand-name medications, even

when payments are of low monetary value (e.g., industry-sponsored meals).⁶ To date, industry payments to physicians involving opioids have not been studied and deserve further examination because they may impede national efforts to reduce overprescribing.

It is currently unclear which opioids are most heavily marketed, to whom, and in exchange for which physician activities. The extent to which abuse-deterrent formulations and nonopioid alternatives are marketed is also poorly understood. For the first time, exhaustive data on payments are now available through the Open Payments program

database implemented under the Physician Payments Sunshine Act.^{5,7} We used this novel data set to characterize industry payments to physicians related to opioid marketing.

METHODS

We extracted all payments between August 1, 2013 (when mandated reporting began), and December 31, 2015, that listed a US Food and Drug Administration (FDA)–approved opioid product. We included buprenorphine but excluded buprenorphine and buprenorphine/naloxone marketed for addiction treatment separately from the buprenorphine transdermal patch marketed for pain control. We excluded remifentanyl (which is marketed exclusively for anesthesia) and 2 fentanyl products (1 marketed exclusively for anesthesia, and 1 marketed exclusively for in-hospital pain).

We also identified payments involving FDA-recognized abuse-deterrent opioid formulations.⁸ For comparison with a nonopioid class of pain medications, we quantified payments for all actively marketed nonsteroidal anti-inflammatory drugs (NSAIDs) in the database. We chose NSAIDs for this comparison because unlike other medication classes used for pain that have additional indications (e.g., medications marketed not only for pain but also for depression or neuralgia), NSAIDs are almost exclusively used for pain control.

We limited the current analysis to non-research payments to physicians; we excluded research payments, which are made in

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association with established research protocols, do not explicitly target prescribing behaviors, and may be provided to physicians not actively practicing medicine. We summarized payments in terms of total dollars and number of payments made and identified changes from 2014 to 2015 (the 2 years for which all 12 months of data were available). We used medians, interquartile ranges (IQRs), and ranges as a result of heavily skewed distributions to examine payments according to opioid product, abuse-deterrent formulation, nature of payment (i.e., physician activity leading to the payment), state, and physician specialty. We also assessed payments to physicians receiving the top 1% of payments for opioids. We used Stata version 13.1 (StataCorp LP, College Station, TX) for analyses.

RESULTS

Over the study period, 375 266 non-research payments involving a marketed opioid were made to 68 177 physicians, totaling \$46 158 388. Total payments increased from \$18 958 125 in 2014 to \$20 996 858 in 2015, an increase of 10.7%. The number of payments increased from 145 715 in 2014 to 184 237 in 2015, an increase of 26.4%.

The 5 opioid products constituting the greatest proportion of payments were fentanyl (\$21 240 794; 46.0% of total dollars), hydrocodone (\$7 123 421; 15.4%), buprenorphine transdermal patch (\$5 141 808; 11.1%), oxycodone (\$4 487 978; 9.7%), and tapentadol (\$4 296 130; 9.3%). Overall, payments for FDA-approved abuse-deterrent formulations totaled \$9 352 959 (20.3%), and payments for buprenorphine or buprenorphine/naloxone marketed for addiction treatment totaled \$4 561 729 (9.9%). By comparison, payments for NSAIDs amounted to \$13 758 385 (not included in previous totals).

Speaking fees or honoraria constituted the largest proportion of payments in dollars, whereas payments involving food and beverage were the most common (Table 1). Payments varied widely according to US state (Figure A, available as a supplement to the online version of this article at <http://www.ajph.org>). The median paid per physician annually was \$15 (IQR = \$7–\$42; maximum = \$1 539 471),

TABLE 1—Characteristics of Payments Involving Opioid Products to Physicians: Open Payments Program Database, United States, August 1, 2013–December 31, 2015

| Nature of Payment | Total Payment Amount, \$ (%) | Median Payment, \$ (IQR) | No. of Payments (%) |
|----------------------------|------------------------------|--------------------------|---------------------|
| Speaking fees or honoraria | 29 190 854 (63.2) | 2 010 (1 000–3 750) | 9 161 (2.4) |
| Food and beverages | 7 872 581 (17.1) | 14 (11–18) | 352 298 (93.9) |
| Consulting fees | 5 886 461 (12.8) | 1 000 (500–2 500) | 2 145 (0.6) |
| Travel and lodging | 2 904 940 (6.3) | 537 (100–1 131) | 4 048 (1.1) |
| Education | 222 869 (0.5) | 14 (5–25) | 7 422 (2.0) |
| Other ^a | 80 683 (0.2) | 100 (14–500) | 192 (0.1) |

Note. IQR = interquartile ranges.

^aIncludes gifts, entertainment, and space rental or facility fees.

with physicians receiving a median of 1 payment annually (IQR = 1–2; maximum = 157). Payments were positively skewed, with the top 1% of physicians (n = 681) receiving \$2639 or more annually (Table A, available as a supplement to the online version of this article at <http://www.ajph.org>). These physicians collectively received \$38 073 796 (82.5% of total payments) during the study period.

Physicians specializing in anesthesiology received the most in total annual payments (median = \$50; IQR = \$16–\$151; n = 4339), followed by physical medicine and rehabilitation (median = \$48; IQR = \$14–\$145; n = 3502) and pain medicine (median = \$43; IQR = \$12–\$125; n = 3090). Physicians specializing in family medicine received the largest total number of payments (n = 20 592).

DISCUSSION

According to the Association of American Medical Colleges, there were 829 962 active physicians in the United States at the beginning of the study period in 2013⁹; thus, our results suggest that 1 in 12 physicians received an industry payment involving an opioid during the 29-month study period. Although half of all the annual payments were \$15 or less, even small payments (including meals) are associated with increased prescribing of marketed products.⁶ FDA-approved abuse-deterrent formulations, which have properties expected to render misuse less likely, constituted only one fifth of the total payments, suggesting that such medications may not be as heavily marketed as other opioids

are. Additionally, despite Centers for Disease Control and Prevention recommendations to consider use of nonopioid medications for pain, NSAIDs, a prominent family of non-opioid pain medications, were not as heavily marketed as opioids were.²

Fentanyl was the most common opioid involved in payments to physicians. National data implicate fentanyl in a rapidly increasing number of overdose deaths, although most are caused by illicitly manufactured fentanyl.¹⁰ Further studies should clarify the extent to which industry payments contribute to prescribing patterns and overdose rates across geographic regions, particularly given the heterogeneity we observed in payments among states. Although payment amounts in dollar terms were greatest to physicians specializing in anesthesiology, physical medicine and rehabilitation, and pain medicine—specialists with expertise in pain management—family medicine physicians received the largest number of payments, indicating extensive marketing of opioid products to primary care physicians. Because there were 108 917 active family physicians in the United States in 2013,⁹ our data highlight that nearly 1 in 5 received an opioid-related payment.

A limitation of this study was the absence of further details about industry-physician interactions; some payments may have supported education on appropriate prescribing behaviors.¹¹ One tenth of the payments involved buprenorphine marketed for addiction treatment, which may have resulted in improved education on addiction care. Risk Evaluation and Mitigation Strategies programs imposed by the FDA require education on extended-release/long-acting

opioids and on transmucosal fentanyl products, and some industry payments to physicians may have been related to this regulation. Another limitation was that some abuse-deterrent formulations were approved part-way through the study period; in future years, such medications might be associated with a greater portion of industry payments.

PUBLIC HEALTH IMPLICATIONS

To our knowledge, this was the first large-scale examination of industry payments involving opioids. Financial transfers were substantial and widespread and may be increasing in number and value. Although opioid prescribing declined nationally during the study period,¹² these results should prompt an examination of industry influences on prescribing amid an ongoing opioid crisis. Further research should examine whether payments are related to opioid misuse and overdose, and policymakers might consider whether caps should be imposed on certain payments. **AJPH**

CONTRIBUTORS

S. E. Hadland and B. D. L. Marshall designed the study and wrote the protocol. S. E. Hadland conducted the literature review and wrote the first draft of the article. M. S. Krieger undertook data management and statistical analyses with additional input from S. E. Hadland and B. D. L. Marshall. All authors contributed to and approved the final article.

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HUMAN PARTICIPANT PROTECTION

The study was considered exempt by the Brown University institutional review board.

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